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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/764,726	01/26/2004	J. David Blaha	702.118	8631

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WRIGHT MEDICAL TECHNOLOGY, INC.
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ARLINGTON, TN 38002-9501

EXAMINER

HOFFMAN, MARY C

ART UNIT	PAPER NUMBER
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3733

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/12/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary

Application No.

10/764,726

Applicant(s)

BLAHA ET AL.

Examiner

Mary Hoffman

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 November 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-27 is/are pending in the application.
- 4a) Of the above claim(s) 5, 11 and 12 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-4, 6-10, 13-20 and 24-27 is/are rejected.
- 7) ☒ Claim(s) 21-23 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 26 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date 12/29/06

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date: _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Objections

Claims 21-23 are objected to because of the following informalities: In newly added claims 21-23, Applicant employs the term "proximal" for the first time in the claims. Previously in the claims, locations have been described using the terms "rearward" and "forward". It is suggested that Applicant employ consistent terminology throughout the claims to be clearer for examination purposes. For the purposes of examination, "proximal" is being considered to be in the rearward direction. Appropriate correction is required.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-4, 6-10, 13-20 and 24-27 are rejected under 35 U.S.C. 103(a) as being unpatentable over Meyer (U.S. Patent No. 4,549,319) in view of Mackwood Ling et al. (U.S. Patent No. 6,241,772).

Meyer discloses a self-rasping prosthetic (see Figs. 5, col. 11, lines 44-48) comprising an elongate body having a central longitudinal axis, a rearward end, a forward end, and a plurality of cutting teeth on a surface of the elongated body and

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being matched to corresponding corners of the prosthetic component, and a distal tip at the forward end of the elongate body. The cutting teeth (jagged portions of fins ref. #28) are along the corner edges, and side walls connect the cutting teeth of adjacent corner edges, the side walls extending inwardly from the cutting teeth in the direction of the central longitudinal axis. The body comprises four corner edges. The components denoted by ref. #28, including the corners edges and sidewalls. The side walls have a concave configuration.

Meyer discloses the claimed invention except for the bullet-shaped distal tip comprising a three fins or four fins fixedly attached, spaced at 90 degrees spaced locations about the central longitudinal axis, extending radial to the central longitudinal axis and extending longitudinally, distally from the forward end of the body to converge at an apex aligned with the central longitudinal axis, the fins being disposed inwardly.

Mackwood Ling et al. disclose a centralizing device for the stem of a prosthesis (see Fig. 4) including a bullet-shaped distal tip comprising a three fins and four fins fixedly attached, spaced at 90 degrees spaced locations about the central longitudinal axis, extending radial to the central longitudinal axis and extending longitudinally, distally from the forward end of the body to converge at an apex aligned with the central longitudinal axis, the fins being disposed inwardly in order to centralize the device at the distal end (col. 3, lines 22-35).

It would have been obvious to one of ordinary skill in the art to construct the device of Meyer with a bullet-shaped distal tip comprising a three fins and four fins fixedly attached, spaced at 90 degrees spaced locations about the central longitudinal

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axis, extending radial to the central longitudinal axis and extending longitudinally, distally from the forward end of the body to converge at an apex aligned with the central longitudinal axis, the fins being disposed inwardly in view of Mackwood Ling et al. in order to centralize the device at the distal end.

Allowable Subject Matter

Claims 21-23 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims and overcome the claim objection above.

Response to Arguments

Applicant's arguments filed 11/15/2006 have been fully considered but they are not persuasive.

Applicant argues that the centralizer plug of Mackwood Ling cannot be combined with the self-rasping femoral prosthetic of Meyer because there is no motivation to combine. Applicant argues that Meyer is a **cementless** prosthesis, and therefore would have no need for a centralizer plug designed for **cemented** prostheses. The examiner respectfully disagrees and refers Applicant to Fig. 4 of the Meyer reference. In Fig. 3, reference #32 illustrates cement. Therefore, the Meyer reference is not "cementless" as claimed by Applicant. Also, in col. 5, lines 60-end and col. 6, lines 60-64, the reference states that the distal stem part of the prosthesis can be advantageously fixed to the canal of the femur using bone cement, or polymethy methacrylate (PMMA). Thus, the

centralizer plug of Mackwood Ling would be useful in stabilizing the cemented distal stem of the prosthesis. Also see col. 1, lines 30-43.

It is also noted that the femur canal is prepared first for the stem, and the self-rasping portion of the prosthesis is only located near the upper region. Unlike suggested by Applicant, the examiner's opinion is that using the centralizer plug of Mackwood Ling with the Meyer reference would not destroy their intended functions, since the rasping-portion of the implant is only necessary to provide a tight fit at the upper regions of the prosthesis. The centralizer would not be involved in the broaching procedure, since the femoral canal adjacent the stem portion will have already been reamed/broached, and only the self-rasping portion of the prosthesis of Meyer broaches the upper portion of the canal.

In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

With regard to Applicant's assertion that the Meyer reference does not show "a prosthetic component with a rectangular cross section" in claim 3, it is noted that the prosthetic component is recited functionally, i.e. "to receive a prosthetic component."

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Thus, this is being treated as a functional statement, and the device of "Meyer need only possess corner edges that are capable of matching corners of a prosthetic component with rectangular cross section. With regard the statement of intended use and other functional statements, they do not impose any structural limitations on the claims distinguishable over Meyer in view of Mackwood Ling, which is capable of being used as claimed if one so desires to do so. *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). Furthermore, the manner in which a device is intended to be employed does not differentiate the claimed apparatus from prior art apparatus satisfying the claimed structural limitations. *Ex parte Masham*, 2 USPQ2d 1647 (1987).

The rejections are deemed proper.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of

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the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mary Hoffman whose telephone number is 571-272-5566. The examiner can normally be reached on Monday-Friday 9:00-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Eduardo C. Robert can be reached on 571-272-4719. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MCH



EDUARDO C. ROBERT
SUPERVISORY PATENT EXAMINER